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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/691,859

10/23/2003

Charmaine K. Harris

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05/14/2009

Intellectual Property Group, MDT Patents
Fredrikson & Byron, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402

EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

05/14/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip@fredlaw.com

rpavey@fredlaw.com

Office Action Summary	Application No. 10/691,859	Applicant(s) HARRIS, CHARMAINE K.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 6-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claim 1, 3-4 and 7 have been considered but are moot in view of the new ground(s) of made in view of the previously cited reference Putz (US 4,903,702).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 3-4 and 6-9 are rejected under 35 USC 103(a) as being unpatentable over Putz (US 4,903,702). Putz discloses a medical lead with an electrode array located on the longitudinal centerline of a generally flat paddle. The paddle has a proximal and distal end with at least one electrode exposed through a first major surface and insulated by a second major surface. The medical lead also includes a radiopaque marker (depicted as 34 in figures 2-4 and 46 in figure 6) to indicate the orientation and position of the contacts located on the paddle.

Although the orientation marker is placed on the longitudinal centerline with at least one electrode, it would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the location of the radiopaque marker since it would have been obvious to one having ordinary skill in the art at the time the invention

was made to have modified Putz to include an orientation marker displaced from the center line, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04). Furthermore, such a relocation of the orientation marker would still provide the predictable results of enabling the clinician to monitor the paddle electrode during implantation, regardless of location on the paddle.

Furthermore, Putz discloses in col. 6, lines 50-55, “radiopaque dielectric markers can be in the form of separate pieces added to the flat constructions as shown, or they can be incorporated within the flexible member in other ways. For example, the flexible dielectric sheets can have radiopaque enhanced portions incorporated therein during their formation processes”. Therefore, the enhanced portions of the paddle would obviously enable a location that is displaced from the centerline and the electrodes.

Additionally, as to claim 1, Putz discloses the device substantially as claim, but is silent about the length of the electrode free portion of the paddle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the portion to be at least 40 mm in order to provide the predictable results of ensuring proper stimulation or sensing to locations deep within the muscular or vasculature. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the length of the electrode free portion, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05). It additionally has been held that

rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04).

As to claim 4, Putz discloses an orientation marker and the specific location of the orientation marker and thus would necessarily enable the identification of the type of lead model. Alternatively, although the examiner considers Putz to disclose an orientation maker to determine the model above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Putz with an orientation marker coded with identification information about the lead since the availability of lead specific data would provide the predictable results of determining system compliance and manufacturing defects.

As to claims 6 and 8, Putz discloses the claimed invention except for radio-opaque material comprising platinum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416 (See MPEP 2144.07). Furthermore, such a modification from one type of radio-opaque material to a different type of radio-opaque material such as platinum, would provide the predictable results of enabling the observation of the lead post implantation and provide a conventional marker.

As to claim 9, Putz discloses the claimed invention except for transparent polyurethane material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials, since it has been held to be

within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416 (See MPEP 2144.07). Furthermore, such a modification from silicone to substantially transparent polyurethane would provide the predictable results of maintaining biocompatible and providing the ability to observe possible defects in the lead paddle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762